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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/993,946 | 12/18/97 | SILVESTRINI | T 251692003600 |
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QM12/1107

EXAMINER

WILLSE, D

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/993,946

Applicant(s)
SILVESTRINI

Examiner
Dave Willse

Group Art Unit
3738



☒ Responsive to communication(s) filed on Sep 22, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17, 20, 21, 23, and 24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17, 20, 21, 23, and 24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claims 8-11, 23, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 8, lines 3-4, the duplicate language "having a side leg through said incision and rotating the pocket-forming dissector blade" should be deleted. In claim 24, line 4, "opening" should apparently be replaced by --open--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 14-17, 20, and 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Peyman, US 5,964,748. Particular attention is directed to column 12, lines 34-40; column 13, lines 32-35; column 15, lines 58-66; and column 17, lines 28-31.

As for claim 1 and others, in the embodiment of Figures 37-45 (column 15, line 30 et seq.), a small incision 418 is cut in the anterior surface of the cornea (column 15, lines 42-47), a

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circular channel originating at one side of the incision **418** is created (column 17, lines 19-31), the circular channel is widened in certain locations to accommodate a ring of non-uniform cross-section (column 18, lines 4-11; column 13, lines 30-39; column 3, lines 58-61; column 17, lines 28-31; column 21, lines 46-49), and the intracorneal implant **430** is introduced into the widened channel through the small incision **418** (column 16, lines 63-67). The distance from the exposed side of the incision **418** to the circular channel can be 1.5 mm or even less (column 15, lines 43-46; column 17, lines 36-38). As another example, in the embodiment depicted in Figure 89 (column 29, lines 45-58), a relatively small arcuate slit **1118** is formed in the exterior surface of the cornea **1112**, a circular intracorneal channel **1120** is created, the circular channel is widened (column 29, lines 54-55), and "an ocular implant can be inserted into the annular pocket" (column 29, lines 56-57).

Regarding claims 2 and 3: column 17, lines 36-40; column 12, lines 35-37; and Figures 41-45. Regarding claims 16, 17, 22, and 23: column 16, line 63, through column 17, line 5. Regarding claim 21, at least the outer surfaces of opposite ends of the flexible, resilient ring shaped member **430** are in a stretched state while in the tool **450**, particularly when the implant is folded (column 16, line 63, through column 17, line 5).

Claims 6, 8-11, 13, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, US 5,964,748. Side legs as set forth in instant claims 6, 8, and 13 would have been obvious from column 13, lines 32-35, and column 15, lines 64-66, in order to accommodate the shape of the ocular material **430** (column 17, lines 28-31; Figure 42), with further motivation

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having been provided by Figures 27 and 36. Regarding claim 24, the tool **450** being arc-shaped would have been obvious in order to match the circular shape of the pocket **426** and/or a curved incision (column 15, lines 43-44).

Claims 4, 5, 7, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peyman, US 5,964,748, in view of Mathis et al., US 5,846,256. To employ the clockwise and counter-clockwise dissectors and channel connectors taught in Mathis et al. would have been obvious in order to provide better matching of the circular intracorneal channel dimensions with those of the ring implant **430** of Peyman, with further motivation to use complementally shaped tools having been provided by column 17, lines 19-22, 28-31, 39-42, and 49-51, of Peyman.

The Applicant's remarks have been reviewed. The Applicant's assertions regarding the rejection under 35 U.S.C 102(e) are believed to be adequately addressed above. As for the rejection under 35 U.S.C. 103(a), it is the examiner's position that a transversely extending member such as a side leg would have been obvious in order to increase the thickness of the pocket in some or all of the regions. The bent end of the fiber optic tip shown in Figure 27 along with the increased thickness of the pocket **126** relative to that depicted in Figure 25, and the widened end of the drill tip **400** (Figure 36) would have suggested to one of ordinary skill the usefulness of transverse leg-like members in forming areas of increased thickness or width. An arc-shaped insertion tool would better conform to the arcuate geometries involved and avoid aggravating or altering the incisions and channel dimensions already produced.


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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is (703) 308-2903. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse
November 3, 2000


DAVE WILLSE
PRIMARY EXAMINER
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